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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,960	03/27/2000	Michael Friedman	104/16	3862

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EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/534,960	Applicant(s) Friedman et al.
Examiner Sharon Howard	Art Unit 1615



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 9/18/01 and 9/19/2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-93 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-93 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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**Receipt of change of address filed on 9/18/01 and Amendment A filed on 9/19/01 have been acknowledged.**

**The 112 (second paragraph) rejection for the claims has been overcome.**

**Claims 1,5,6,9,10,13,14,16,17,19,20,  
22-28,28,30,38,39,44,47,50,51,54,55,58,59,61,62,64,65,67-72,75,76,84,85,90 and 93 have been  
amended.**

**Claims 1-93 are pending in this application.**

**In view of applicant's arguments filed on 9/19/01, the rejection set forth in paper  
no.6 is deemed to be moot.**

#### **DETAILED ACTION**

##### ***Claim Rejections - 35 USC § 112***

1. Claims 1,6,47 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 47 and 93, the phrase "a prolonged effect therapeutic nail varnish composition" is vague and indefinite. It is suggested by the examiner that applicant remove said phrase and insert "A sustained-release therapeutic nail varnish composition".

2. Claim 6 recites the limitation "the non-volatile components". There is insufficient antecedent basis for this limitation in the claim.

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***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohn (U.S. Patent No. 5,264,206) in view of Friedman ('737).

Bohn teaches a nail lacquer composition which is known in the art for treating mycoses of the nails (col.1, lines 6-54 and col.2, lines 46-68), comprising antifungal agents consisting of econazole, miconazole and naftifine hydrochloride (see Abstract, col.3, lines 15-68 and the TABLE at col.6, EXAMPLE 1-6), volatile solvents (col.4, lines 46-68, bridging col.5, lines 1-8), additives which are excipients (col.5, lines 9-16), lanolin derivatives, urea and allantoin which have humectant properties (col.5, lines 9-20), water (col.6, EXAMPLES 7-9), film forming agents which include copolymers of methyl vinyl ether, copolymers of acrylic acid and methacrylic acid (col.2, lines 58-68, bridging col.3, lines 1-11) and keratolytic agents (i.e. salicylic acid)(col.5, lines 17-20).

Bohn does not teach a prolonged effect therapeutic nail varnish composition. However, Friedman discloses a liquid methacrylic acid polymer composition containing sustained-release of pharmacological active agents (see Abstract) which are known in the art for treating dermatological conditions of the skin (col.21, lines 13-34), wherein the active agents

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comprises fungal, bacterial and viral agents (col.7, lines 8-64), antifungal and an antiviral agent (col.8, lines 42-56), about 1% of a plasticizer, dibutyl phthalate or PEG (col.16, lines 18-27), water, ethyl alcohol (col.9, lines 5-13 and col.11, lines 63-65), clotrimazole, miconazole nitrate, fluconazole, ketoconazole, tolnaftate or nystatin (col.13, lines 34-47), antibacterials (erythromycin, clindamycin, gentamycin, neomycin or tetracycline) and antivirals (acyclovir, amantadine or ribavirin (col.14, lines 4-7). Friedman discloses that the agent is embedded in a sustained-release carrier comprising a hydrophobic acrylic polymer (i.e. methacrylic acid type A copolymer) or an acrylic polymer, in a pharmaceutically acceptable vehicle (col.11, lines 57-61 and col.15, line 33). Friedman also teaches using about 1% of humectants (glycerol, sorbitol or mineral oil (col.16, lines 18-21) and that one skilled in the art would be able to produce the particular amount of each of the agents and the sustained release polymer (col.16, lines 38-40).

The method of making the sustained release composition is an obvious process known in the pharmaceutical art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a sustained release composition taught by Friedman which is known in the art for treating conditions of the skin, in a nail varnish composition taught by Bohn et al, with the expectation of achieving a composition for treating conditions of the skin and mycoses of the nails. One would expect to achieve similar results.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Howard whose telephone number is (703) 308-4359. The examiner can normally be reached Monday through Friday from 9:00am to 5:00pm.

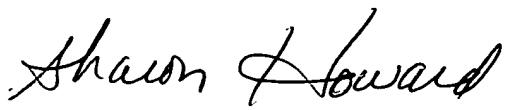
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 746-3121.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sharon Howard

November 30, 2001

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SUPERVISORY PATENT EXAMINER  
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